

**29 May 2017**

Pre-Conference  
Workshop

**The Principles of  
Viral Safety for  
Biologics and  
Vaccines**

**2017 PDA Europe Conference, Exhibition**

# **Virus & TSE Safety Forum**

**30 May – 1 June 2017**

Sheraton Dubrovnik Riviera Hotel  
**Dubrovnik | Croatia**

Dear Colleagues,

The Program Planning Committee and an impressive panel of selected speakers warmly invite you to Dubrovnik / Croatia! We are pleased and grateful to once again come together for the **2017 PDA Europe Virus & TSE Safety Forum!**

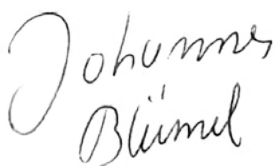
This conference was established in 2001 and, held annually since then, alternates between Europe and the U.S. These truly global meetings are organized under the leadership of PDA in close cooperation with European regulatory agencies and the U.S. FDA. They provide an overview and updates on regulatory expectations and scientific investigations related to virus and TSE safety of biotechnology, plasmaderived and cell-derived medicinal products.

As in previous years, virus contamination of raw materials as well as emerging viral threats will be discussed. Appropriate risk mitigation strategies consisting of two elements: i.) Testing and processing of raw materials and ii.) Virus removal/inactivation capacity of the processes used for production of medicinal products will be taken into consideration. The last day of the conference will focus on TSE and how much vCJD or BSE currently pose a threat to the safety of medicinal products.

This PDA Europe Virus & TSE Safety Forum always provides attendees a unique opportunity for interactive discussion and benchmarking. Exchange of information between industry and regulators will improve the understanding and acceptance of new techniques, highlight new and emerging risks and explain new regulatory approaches.

Panel Discussions, luncheons, dinners and a networking event will hopefully complete this impressive program and make it into a worthwhile and well-rounded learning experience for you!

We warmly invite you to join us in Dubrovnik, a World Heritage Site on the Adriatic Sea, rich in history and culture.



**Johannes Blümel**, PhD, Paul-Ehrlich-Institut, Chair

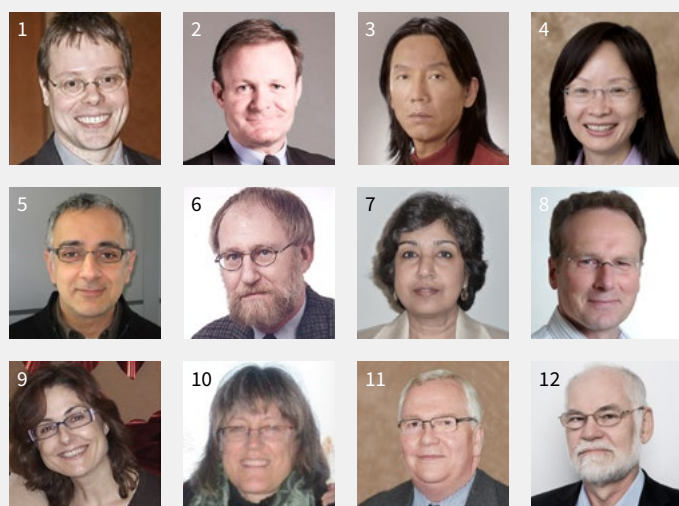


**Thomas R. Kreil**, PhD, Shire, Co-Chair



<b>29 May</b>	<b>9:00 – 17:00</b>	<b>The Principles of Viral Safety for Biologics and Vaccines</b>	<b>Pre-Conference Workshop</b>
<b>30 May</b>	<b>9:00 – 18:30</b>	<b>Virus &amp; TSE Safety Forum</b>	<b>Conference, Exhibition</b>
<b>31 May</b>	<b>7:30 – 17:00</b>		
<b>1 June</b>	<b>9:00 – 13:30</b>		

For latest information, please visit: **[pda.org/eu-virus2017](http://pda.org/eu-virus2017)**



## SCIENTIFIC PROGRAM PLANNING COMMITTEE

- 1 Johannes Blümel**, Chair, Paul Ehrlich Institut
- 2 Thomas R. Kreil**, Co-Chair, Shire
- 3 Dayue Chen**, Eli Lilly
- 4 Qi Chen**, Genentech
- 5 Houman Dehghani**, Amgen
- 6 Albrecht Gröner**, PathoGuard Consult
- 7 Arifa Khan**, US FDA
- 8 Michael Ruffing**, Boehringer-Ingelheim
- 9 Sol Ruiz**, AEMPS
- 10 Dorothy Scott**, US FDA
- 11 Martin Wisher**, BioReliance
- 12 Georg Roessling**, PDA Europe

# The Principles of Viral Safety for Biologics and Vaccines

This workshop will provide an overview of two important viral safety barriers – testing and viral clearance approaches. Typically applied testing methods, the benefits and downsides, and some product type specific testing strategies will be presented briefly. The frequently discussed NGS technology and its use in this field will be explained in a simple way. With this background specific applications and testing strategies for critical raw materials, ATMPs, and even medical devices using animal/human derived components will be discussed.

In the second part, important aspects of viral clearance studies like pre-testing, virus assays, viral loads, etc., will be presented and critically reviewed. An overview of the viral removal or inactivation capacity of typically applied process steps will also be given and discussed using case studies. The workshop will consider current best practice including the current regulatory requirements.

It is the intention of the workshop to introduce typical testing strategies and typical viral clearance approaches. The workshop will give much room for discussions and participants are invited to ask questions related to their specific products, their viral safety strategies, or any specific technical or regulatory challenges they have. The speaker panel combines long term regulatory experience, industry experience and contract testing laboratory experience, all to ensure maximal outcome for attendees.

## Panel Discussion

Virus Safety Requirements of Raw Materials is one of the topics discussed controversially. PDA aims to collect feedback here and approach the European Medicines Agency to include these in a Q&A of the respective Guidelines.

If you have questions, feedback or topics you would like to see addressed, please e-mail them to [programs-europe@pda.org](mailto:programs-europe@pda.org)

**Monday, 29 May 2017****9:00 Welcome and Introduction**Georg Roessling, *PDA Europe*  
Horst Ruppach, *Charles River*,  
*Workshop Chair***Plenary 1: Virus Safety Testing****9:15 Standard/Compendial Methods**Michael Ruffing,  
*Boehringer Ingelheim***9:45 Next Generation Sequencing (NGS)**Martin Wisher,  
*BioReliance***10:15 Coffee Break****10:45 Testing Strategies: Cell Bank Characterization,  
Bulk Harvest Testing, Raw Material Testing including  
Animal/Human Derived Aids used by ATMP Industry**James Gombold,  
*Charles River***11:15 Q&A, Discussion****12:00 Lunch Break****Plenary 2: Viral Clearance****13:00 Regulatory Background: ICH, FDA, EMA Regulations and  
their Applicability to Different Products including ATMPs**Johannes Blümel,  
*Paul-Ehrlich-Institut***13:30 Practical Aspects of Viral Clearance Studies:  
Viral Quantification Assays, Pre-testing, Virus Spike**Johanna Kindermann,  
*Shire***14:00 The Effectiveness of Typically Applied Process Steps:  
Chromatography, Virus Retentive Filtration, Inactivation by low pH,  
Solvent/Detergent, Gamma Irradiation, etc.**Johannes Blümel,  
*Paul-Ehrlich-Institut***14:30 Coffee Break****15:00 Case Study: Viral Clearance Studies for Cell Line Derived  
Recombinant Products, Raw Materials, ATMPs, Medical Devices**Horst Ruppach,  
*Charles River***15:30 Panel Discussion &  
Day's Conclusion**Panelists:  
All Speakers  
US FDA  
Volunteer Attendees**17:00 End of Pre-Conference Workshop**

## Tuesday, 30 May 2017

### 9:00 Welcome and Introduction

Georg Roesslering, *PDA Europe*  
Johannes Blümel, *Co-Chair,*  
*Paul-Ehrlich-Institut*  
Thomas R. Kreil, *Co-Chair, Shire*

### Session 1: Regulatory Developments

*Moderator: Houman Dehghani, Amgen*

### 9:10 Update on European Regulations

Johannes Blümel,  
*Paul-Ehrlich-Institut*

### 9:40 Convalescent Plasma for Immune Globulins – Viral Safety Issues

Dorothy Scott,  
*US FDA*

### 10:10 Validation of Virus Reduction at Continuous Processing

Scott Lute,  
*US FDA*

### 10:40 Panel Discussion

### 11:00 Coffee Break, Poster Session & Exhibition

### Session 2: Hepatitis E Virus

*Moderator: Thomas R. Kreil, Shire*

The circulation of hepatitis E virus (HEV) as food-borne pathogen has only recently been recognized in industrialized countries. Infections remain mostly asymptomatic, as evidenced by high seroprevalence rates but low numbers of clinical case reports. HEV has, however, also been transmitted by transfusion of labile blood products, and has occasionally been detected in plasma pools for fractionation. It has thus been considered necessary to verify the safety margins of plasma products with respect to HEV, as primarily afforded by virus reduction steps embedded into their manufacturing processes.

### 11:30 Non-enveloped Viruses with a Lipid Envelope: Presence in Plasma and 'Model' Virus Preparation for Virus Reduction Studies

Maria Farcet,  
*Shire*

### 12:00 Hepatitis E Virus Stability Determination in Food – Achievements and Challenges

Reimar John, *Federal Institute for Risk Assessment*

### 12:30 Development of a Relevant Model Virus System, Cutthroat Trout Virus, for Hepatitis E Virus Clearance Studies

Nathan Roth,  
*CSL Behring*

### 13:00 Q & A, Discussion

### 13:30 Lunch Break, Poster Session & Exhibition

### Session 3: Viral Risk Mitigation Strategies

*Moderator: Albrecht Gröner, PathoGuard*

Virus contaminations of biotechnology products derived from carefully tested and selected cell banks may arise from virus contaminated raw materials as cell culture media and by cross contamination of products. Risk mitigation strategies such as appropriate segregation of product intermediates within and between batches and inactivation / removal of adventitious viruses in raw materials will be presented.

<b>14:30</b>	<b>Industry Approaches to Facility Segregation for Viral Safety</b>	Paul W. Barone, <i>Massachusetts Institute of Technology, Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB)</i>
<b>15:00</b>	<b>New Quantitative, Risk-based Approach to Appropriate Viral Segregation Measures</b>	Kavita Ramalingam Iyer, <i>Merck Sharp &amp; Dohme</i>
<b>15:30</b>	<b>Retrospective Evaluation on the Necessity of End of Use Resin Viral Clearance Studies - A Multiple Company Collaboration</b>	Konstantin Zöller, <i>Novartis Pharma, BioPhorum Development Group Viral Clearance Working Team</i>
<b>16:00</b>	<b>Mitigation of Risk of Viral Contamination of Media using Upstream Barrier Methods</b>	Kathryn Martin Remington, <i>BioReliance</i>
<b>16:20</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
<b>17:00</b>	<b>Minute Virus of Mice - Non-susceptible CHO Cell Line</b>	Kevin Kayser, <i>Merck KGaA</i>
<b>17:20</b>	<b>Defend Your Bioreactor: Using Nanofiltration to Prevent Virus Contamination of Cell Culture Processes</b>	Christina Carbrello, <i>Merck Group</i>
<b>17:40</b>	<b>Virus Risk Mitigation in Cell Culture Media – New Solutions</b>	Anika Manzke, <i>Sartorius Stedim Biotech</i>
<b>18:00</b>	<b>Q &amp; A, Discussion</b>	
<b>18:30</b>	<b>End of Day 1</b>	
<b>19:00</b>	<b>Networking Reception</b>	

## Wednesday, 31 May 2017

### MORNING SESSION

#### Interest Group Meeting: Advanced Virus Detection Technologies

- OPEN TO ALL -

Moderators: **Arifa Khan, US FDA**  
**Jean-Pol Cassart, GSK**

The Advanced Virus Detection Technologies Interest Group (AVDTIG) is comprised of experts representing industry, academia, government agencies and regulators who discuss the current thinking and planned efforts regarding application of new technologies for virus detection in biologicals. The group's current focus is on next generation sequencing. The session will include brief presentations on the IG history, ongoing activities, and achievements followed by audience participation for Q & A and discussions on additional topics on advanced virus detection technologies for consideration by the IG.

**7:30** **Update on IG Activities**  
**Open Forum and Discussion, Q&A**

**8:45** **Welcome Coffee**

## Session 4: Methods for Virus Detection

Moderator: **Arifa Khan, US FDA**

The “traditional” assays have generally been effective for demonstrating absence of adventitious viruses; however, they may not be sufficiently broad to detect viruses that are distant to known viruses or novel viruses. Virus detection by the routinely used cell culture and molecular methods, and the advanced next generation sequencing technologies will be presented.

<b>9:00</b>	<b>Update on NGS Efforts for Virus Detection</b>	Arifa Khan, <i>US FDA</i>
<b>9:30</b>	<b>Performance of Transcriptomic Analysis by NGS for the Detection of Viral Infection in Cells</b>	Marc Eloit, <i>PathoQuest</i>
<b>10:00</b>	<b>Detection of Different MMV Strains by Cell Culture and PCR Assays, and MMV Permissiveness of Cell Lines used in Biotechnology: How much do we really know?</b>	Thomas R. Kreil, <i>Shire</i>
<b>10:30</b>	<b>Comparing Classical vs New Assays</b>	Siemon Ng, <i>Sanofi</i>
<b>11:00</b>	<b>Q &amp; A, Discussion</b>	
<b>11:30</b>	<b>Lunch Break, Poster Session &amp; Exhibition</b>	

## Session 5: Virus Filtration

Moderator: **Martin Wisher, BioReliance**

The use of virus filtration in the processing of biological products is considered a robust and well accepted component of a virus clearance strategy. This session will provide new data on a number of topics related to the use of this technology including virus retention mechanisms, effects on virus reduction factors of different model parvoviruses, effects of process fluid properties, processing parameters and depressurization/re-pressurization, development of a new nano-cellulose based membrane, and the application of QbD to virus removal by filtration.

<b>13:00</b>	<b>Differential Retention of Animal Parvoviruses during Virus Filtration</b>	Thomas Nowak, <i>CSL Behring</i>
<b>13:20</b>	<b>Retention Mechanisms in Virus Filtration: Membrane Contribution by Size Exclusion and Interactions Between Membrane, Viruses and Solutes under Varied Buffer Conditions</b>	Björn Hansmann, <i>Sartorius Stedim Biotech</i>
<b>13:40</b>	<b>Understanding Virus Filtration and Designing Viral Clearance Studies to Accurately Assess Parvovirus Removal Capability</b>	Daniel Strauss, <i>Asahi Kasei</i>
<b>14:00</b>	<b>Demonstration of Effective Control of Viral Filtration Unit Operation to Adequately Address the Safety Concern Raised by Health Authorities</b>	Dayue Chen, <i>Eli Lilly</i>
<b>14:30</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	
<b>15:00</b>	<b>Multiple, Deliberate Interruptions of a Virus Removal Filtration Process – Impact on Virus Retention and Throughput</b>	Konstantin Zöller, <i>Novartis Pharma</i>
<b>15:20</b>	<b>Nano-cellulose-based Small-size Virus Retentive Filters</b>	Albert Mhramyan, <i>Uppsala University</i>



<b>15:40</b>	<b>Application of Quality by Design (QbD) Principles for Validation of Virus Removal by Filtration</b>	Morven MacAlister, <i>PALL Life Sciences</i>
<b>16:00</b>	<b>Q &amp; A, Discussion</b>	
<b>17:00</b>	<b>End of Day 2</b>	

## Thursday, 1 June 2017

### Session 6: Virus Clearance

Moderator: **Qi Chen**, *Genentech*

Triton X-100 is a widely used detergent for enveloped virus inactivation. Due to environmental concerns of Triton X-100 degradation product, its use in the EU might be restricted through REACh. In this session, the current status and potential impact of the REACh authorization for Triton X-10 on biologics manufacturing in EU, as well as virus inactivation data from eco-friendly detergents will be discussed. Another hot topic in biologics manufacturing is continuous processing. Application of low pH virus inactivation and virus filtration in continuous processing will be presented.

<b>9:00</b>	<b>Advocacy Efforts in Response to Anticipated REACh Regulation on Triton X-100</b>	Marie Murphy, <i>Eli Lilly</i>
<b>9:30</b>	<b>An Alternative “Eco-Friendly” Detergent to Triton X-100</b>	Lenore Norling, <i>Genentech</i>
<b>10:00</b>	<b>Continuous Viral Clearance for the Production of mAbs</b>	Laura Holtmann, <i>INVITE</i>
<b>10:30</b>	<b>Q &amp; A, Discussion</b>	
<b>11:00</b>	<b>Coffee Break, Poster Session &amp; Exhibition</b>	

### Session 7: TSE Safety

Moderator: **Dorothy Scott**, *US FDA*

Existing and emerging TSEs still present potential risks to safety of biological products. This session provides an update on human and animal TSE surveillance, including information about atypical BSE. Measures that reduce TSE risk in manufacturing include safe sourcing of raw materials, and use of decontamination methods that are effective against TSE agents. Methods for inactivation of prions exist but are often harsh and not always suitable for laboratory or manufacturing environments. A new chemical method to inactivate prions, as measured by RT-QuIC will be presented and discussed.

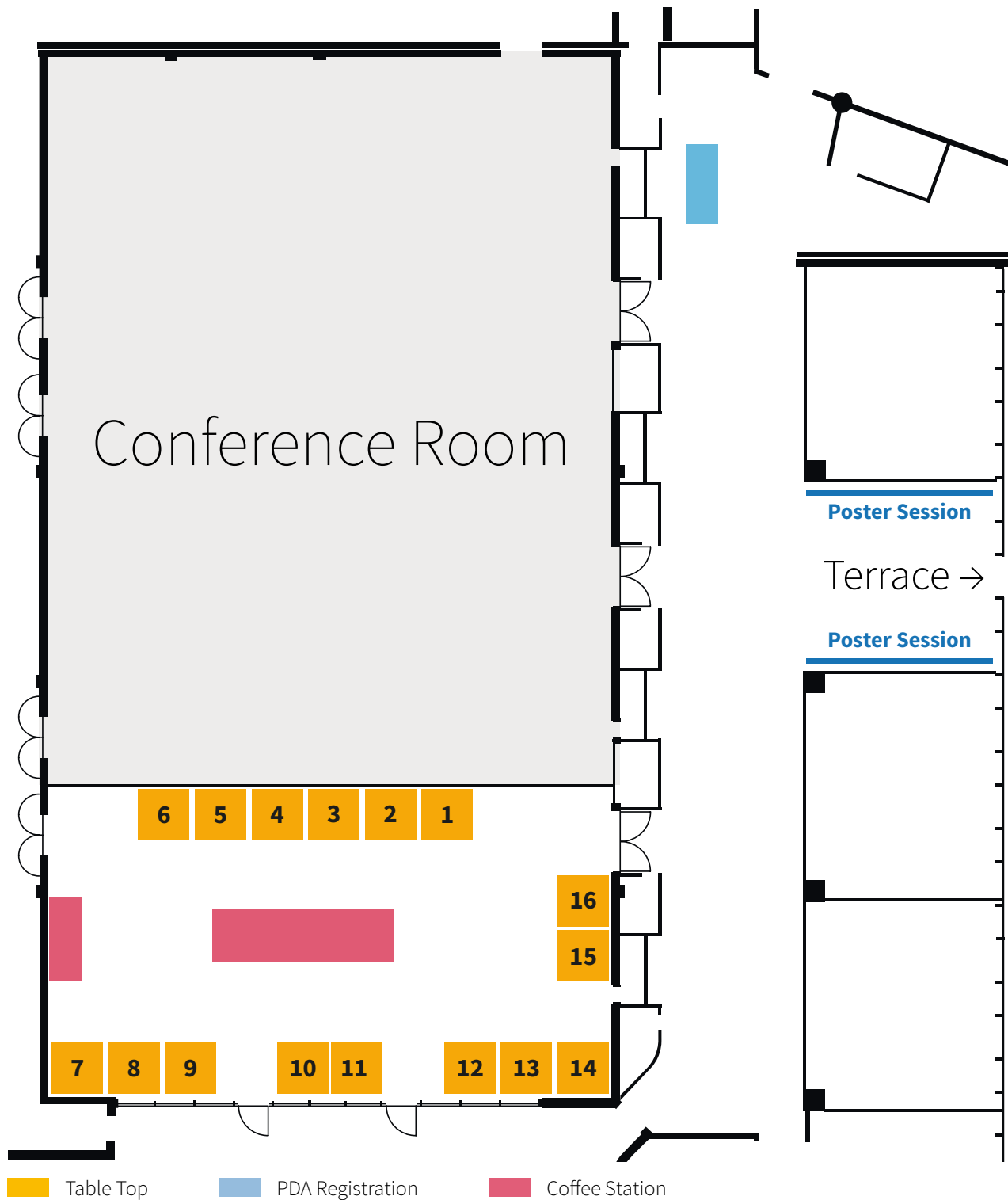
<b>11:30</b>	<b>Surveillance (human) Including Appendix Studies, and Confirmed MV Case</b>	Robert Will, <i>University of Edinburgh</i>
<b>12:00</b>	<b>Inactivation of Prions with Hypochlorous Acid (RT-QuIC)</b>	Byron Caughey, <i>NIH</i>
<b>12:30</b>	<b>The Current Risk of Atypical BSE</b>	Torsten Seuberlich, <i>University of Bern</i>
<b>13:00</b>	<b>Q &amp; A, Closing Panel Discussion</b>	
<b>13:30</b>	<b>End of Conference, Farewell Lunch</b>	

# NETWORKING RECEPTION

Tuesday, 30 MAY | 19:00 H



Join us and your colleagues to enjoy drinks and conversation in a relaxing atmosphere.



### TO EXHIBIT:

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

A basic exhibition package for this event is priced **1.895 Euro net (table-top)**. Sponsorship Packages are available, for more information please contact [expo-europe@pda.org](mailto:expo-europe@pda.org)

## VENUE

### **Sheraton Dubrovnik Riviera Hotel**

Šetalište Dr. Franje Tuđmana 17  
Srebreno  
Mlini, 20207  
Dubrovnik, Croatia  
Tel: +385 20 601 500  
[www.sheratondubrovnikriviera.com](http://www.sheratondubrovnikriviera.com)

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

## DIRECTIONS

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## CONTACT INFORMATION

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13507 Berlin, Germany  
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## CONFERENCE REGISTRATION HOURS

**Monday, 29 May: 7:30 - 10:00**

**Tuesday, 30 May: 7:30 - 10:00**

## SPECIAL REQUIREMENTS



If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to [registration-europe@pda.org](mailto:registration-europe@pda.org).



### **Special offer: Discounted travel with Lufthansa Group Airlines**

Lufthansa Group Partner Airlines offer a comprehensive global route network linking major cities around the world. We offer special prices and conditions to participants, visitors, exhibitors, invited guests as well as employees of the Contracting partner and their travel companions. To make a reservation, please click on **[www.lh.com/event-flight-booking](http://www.lh.com/event-flight-booking)** and enter the access code **DEZJPRH** in the "Access to Your Special Lufthansa Offer" area. This will open an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

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## 3 WAYS TO REGISTER

- 1 **ONLINE:** [pda.org/eu-virus2017](http://pda.org/eu-virus2017)  
2 **FAX:** +49 30 4365508-66  
3 **EMAIL:** [registration-europe@pda.org](mailto:registration-europe@pda.org)

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

### 1 Your Contact Information

If this form is an update to a previously submitted form, please check here. ☐

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### Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

### 2 Registration

All fees given in Euro and excluding VAT (25 %) net

#### Conference (30 May–1 June)

PDA Member	<input type="checkbox"/>	<b>1795</b>
Nonmember**	<input type="checkbox"/>	<b>2095</b>
Govern./Health Authority/Academic**	<input type="checkbox"/>	<b>900</b>
*Early Bird 800 €		

☐ **Poster Presenter please mark here** (written approval required, conference fee applies)

#### Pre-Conference Workshop (29 May)

##### The Principles of Viral Safety for Biologics and Vaccines

All Participants	<input type="checkbox"/>	<b>795</b>
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**\*\*Registration fee includes a one-year PDA membership** if no further special discount is granted. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies). ☐

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation. PDA Europe has secured a limited number of rooms at a special group rate.

**Group Registration Discount** Register 5 colleagues for the conference at the same time and receive the **5th registration free**. For more information on group discounts please contact us at [registration-europe@pda.org](mailto:registration-europe@pda.org). Other discounts cannot be applied.

☐ **Discount for Exhibiting Companies** Please mark here if your company is an exhibitor to this event and you will receive the conference ticket at the **special price of 995 Euro per ticket**. No further discounts are applicable with this option (as PDA Membership Discount or Group Ticket discount). This special rate does not include one-year PDA membership.

### 3 Payment Options

#### ☐ By Credit Card

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**For your credit card information safety:**

**Please send your details by fax only (+49 30 4365508-66) or register online.**

#### ☐ By Bank Transfer

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Date Mandatory Signature

**CONFIRMATION:** Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **2 April 2017** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at [registration-europe@pda.org](mailto:registration-europe@pda.org) or fax to +49 30 4365508-66. **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.



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